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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndt	0050/49860	8414

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KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,313

Applicant(s)

BERNDL ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Edgren et al (USPN 5006346). The claims are drawn to an excipient in powdered form comprising a pharmaceutically acceptable polymer and liquid or semisolid surface-active agent. Edgren teaches a drug deliver system with a powdered medicament. The compound of Edgren comprises a hydrophilic polymer (polyvinylpyrrolidone), an emulsifying surface-active agent measuring 0.01% to 20% weight of the total composition (column 6, lines 8-15; column 8, lines 60-68). These disclosures along with others leave the claimed invention anticipated.
3. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al (USPN 5670158). The reference teaches a compound comprising a carrier polymer (vinylpyrrolidone), and a surface-active agent with an HLB from 6 to 18, preferably 10-16, and is liquid at 37°C. Also the reference teaches that the solid dispersion can be spray dried (Abstract; column 4, lines 36-61; column 5, lines 9-25; column 6, lines 35-40). These disclosures along with others leave the claimed invention anticipated.
4. Claims 1, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Lippmann et al (USPN 4259315). Lippmann teaches a controlled release formulation comprising a polymer carrier and a hydrophilic surfactant surface-active agent having HLB values that exceed 10.

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These surface-active agents are suggested to be those of claim 6 (Abstract; column 5, lines 4-25).

These disclosures along with others leave the claimed invention anticipated.

5. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Straub et al (USPN 5853698). Straub teaches pharmaceutical composition comprising a polymer carrier and a surface-active surfactant, namely glycerol-polyoxyethylene ricinoleate. The reference goes onto teach that the composition can be prepared through a spray-drying procedure (Abstract; column 6, lines 31-48; column 8, lines 15-31; column 9, lines 9-11). These disclosures along with others leave the claimed invention anticipated.

6. Claims 1, 3, 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bar-Shalom et al (USPN 5618560). The reference teaches a controlled release formulation comprising a polymer carrier, an emulsifier having HLB value in the range from 4 to 16, and measuring between 2% to 50% in concentration. Bar-Shalom also goes on to teach that for the preparation of this composition comprising the polymer and surface-active agent, a homogeneous melt can be extruded and further layered into its final presentation (Abstract; column 11-12, lines 57-5). These disclosures along with others leave the claimed invention anticipated.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edgren et al (USPN 5006346), Davis et al (USPN 5670158), and Lippmann et al (USPN 4259315) all in view of Straub et al (USPN 5853698) and Bar-Shalom et al (USPN 5618560). As previously discussed in the *102 b* discussion these references all disclose essential elements of the claimed invention. Each reference teaches the theory of combining a carrier polymer with a surface-active agent. Edgren specifically combines polyvinylpyrrolidone with a surfactant; Davis combines a polymer with a surface-active agent with a HLB between 6 and 18; Lippmann teaches the combination of carrier polymers with ethoxylated sorbitan fatty acid esters. In addition to teaching the basic theory of combining a carrier polymer and a surface-active agent, Straub and Bar-Shalom also teach that these combinations can be prepared through spray-drying or through a homogeneous melt process.

One of ordinary skill in the art would have been motivated to combine any of the polymer carriers of Edgren, Davis, or Lippmann with the processes of Straub or Bar-Shalom. Substituting the surface-active agents of Davis and Lippmann into the compound of Edgren would provide sufficient lubrication to the mixture. Processing this compound according to Straub would provide increased particle dispersion, further processing this compound according

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to Bar-Shalom would allow increase the conformity and uniformity of the compound. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings in the way with the expected result of a sufficiently lubricated, uniform compound able to carry a variety of water-insoluble or soluble active agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-308-1235 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-5014.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
May 8, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600